K046010

JUL 1 9 2004

Attachment 19
510(k) Summary for the Genesis Medical Interventional™
F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System

I. General Information

Submitter:	Genesis Medical Interventional, Inc. #1 Uccelli Blvd., PO Box 246 Redwood City, CA 94063
Contact Person:	Anne C Worden VP, Regulatory & Quality Assurance
Summary Preparation Date:	December 31, 2003

II. Names

Device Names:	Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System
Primary Classification Name:	Embolectomy Catheter

III. Predicate Devices

- Embolectomy Irrigation-Occlusion Balloon Catheter (EIOBC) manufactured by J-Lloyd Medical (K974335);
- Over the Wire Embolectomy Catheter manufactured by LeMaitre Vascular (K022145);
- Dual Lumen Graft Cleaning Catheter manufactured by Applied Medical Resources (K973465);
- MSD Embolectomy Basket manufactured by Metamorphic Surgical Devices (K991093);
- Versa-Cath Arterial Catheter manufactured by Ideas for Medicine (K961883);
- Biosensors Embolectomy Catheter manufactured by Sunscope International (K973477);
- Core and Coil Assembly (CCA) Guidewires manufactured by Lake Region Manufacturing (K971322);
- Mandrel Guidewire Assembly manufactured by Lake Region Manufacturing (K011084).

IV. Product Description

The Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System is comprised of the following main components:

- Expanding Basket Thrombectomy Guidewire;
- Funnel Sheath Catheter;
- Dilator;
- Funnel Sheath Catheter/Dilator assembly Tip Cover
- Accessories – 18 gauge needle and vacuum syringe.

V. Indications for Use

The Genesis Medical Interventional™ F.A.S.T. ™ (Facilitated Aspiration/Suction Thrombectomy) System is indicated for the non-surgical removal of emboli and thrombi from blood vessels, the non-surgical removal of thrombi from synthetic grafts, use in temporary blood vessel/graft occlusion, injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft, and catheter placement over a guidewire.

VI. Rationale for Substantial Equivalence

The Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System shares the same or similar indications for use, device operation, overall dimensions, materials, sterilization process, and packaging, and therefore are substantially equivalent for use in minimally invasive vascular applications to the predicate Embolectomy Irrigation-Occlusion Balloon Catheter (EIOBC) manufactured by J-Lloyd Medical (K974335), the currently marketed predicate Over the Wire Embolectomy Catheter manufactured by LeMaitre Vascular (K022145), the predicate Dual Lumen Graft Cleaning Catheter manufactured by Applied Medical Resources (K973465), the predicate MSD Embolectomy Basket manufactured by Metamorphic Surgical Devices (K991093), the predicate Versa-Cath Arterial Catheter manufactured by Ideas for Medicine (K961883), the predicate Biosensors Embolectomy Catheter manufactured by Sunscope International (K973477), the predicate Core and Coil Assembly (CCA) Guidewires manufactured by Lake Region Manufacturing (K971322), and the Mandrel Guidewire Assembly manufactured by Lake Region Manufacturing (K011084). In addition, validation data demonstrated adequate device performance.

VII. Safety and Effectiveness Information

Performance data was provided to demonstrate that the Genesis Medical Interventional™ F.A.S.T. ™ (Facilitated Aspiration/Suction Thrombectomy) System components perform in accordance with their specifications.

VIII. Conclusion

The Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/Suction Thrombectomy) System was found to be substantially equivalent to the predicate Embolectomy Irrigation-Occlusion Balloon Catheter (EIOBC) manufactured by J-Lloyd Medical (K974335), the currently marketed predicate Over the Wire Embolectomy Catheter manufactured by LeMaitre Vascular (K022145), the predicate Dual Lumen Graft Cleaning Catheter manufactured by Applied Medical Resources (K973465), the predicate MSD Embolectomy Basket manufactured by Metamorphic Surgical Devices (K991093), the predicate Versa-Cath Arterial Catheter manufactured by Ideas for Medicine (K961883), the predicate Biosensors Embolectomy Catheter manufactured by Sunscope International (K973477), the predicate Core and Coil Assembly (CCA) Guidewires manufactured by Lake Region Manufacturing (K971322), and the Mandrel Guidewire Assembly manufactured by Lake Region Manufacturing (K011084). The Genesis Medical Interventional™ F.A.S.T. ™ (Facilitated Aspiration/Suction Thrombectomy) System shares similar indications for use, design features, and similar functional features, and thus is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2004

Genesis Medical Interventional, Inc.
c/o Ms. Anne Worden
V.P. Regulatory & Quality Assurance
652 Bair Island Road, Suite 103
Redwood City, CA 94063

Re: K040010
Genesis Medical Interventional™ F.A.S.T.™ System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: DXE
Dated: June 3, 2004
Received: June 7, 2004

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications for Use Statement as Requested By FDA

510(k) Number (if Known): K040010

Device Name: Genesis Medical Interventional™ F.A.S.T.™ System

Indications for Use:

The Genesis Medical Interventional™ F.A.S.T.™ (Facilitated Aspiration/ Suction Thrombectomy) System is indicated for:

- The non-surgical removal of emboli and thrombi from blood vessels.
- The non-surgical removal of thrombi from synthetic grafts.
- Use in temporary blood vessel/graft occlusion.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vessel/graft.
- Catheter placement over a guidewire.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vuchard
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040010